



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/757,551

01/15/2004

Orhun K. Muratoglu

49931-0085

3038

61263 7590 06/08/2007
PROSKAUER ROSE LLP
1001 PENNSYLVANIA AVE, N.W.,
SUITE 400 SOUTH
WASHINGTON, DC 20004

EXAMINER

DANIELS, MATTHEW J

ART UNIT

PAPER NUMBER

1732

MAIL DATE

DELIVERY MODE

06/08/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/757,551	Applicant(s) MURATOGLU ET AL.	
	Examiner Matthew J. Daniels	Art Unit 1732	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-77 and 80 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-77 and 80 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>3/12/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Please note that this application has been transferred to Matthew J. Daniels.

Response to Amendment

2. There were no amendments made in the reply filed 12 March 2007.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-2, 5-19, 21-35, 38-40, and 77 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lidgren *et al.* (US Patent No. 6,448,315) in view of Hahn (US Patent No. 5,827,904) and Higgins (USPN 5753182).

Lidgren *et al.* ('315) teach the basic process for making a medical implant including, providing UHMWPE powder, mixing said powder with vitamin E (antioxidant) to reduce oxidation, irradiating said mixture with radiation, compression molding said irradiated mixture into said medical implant or machining medical implants from compression molded blocks of said irradiated mixture, packaging said medical implant and sterilizing said package (see col. 4, line 45 through col. 5, line 10 and col. 5, line 66 through col. 6, line 8). Further, it is submitted that Lidgren *et al.* ('315) teach reducing the free radicals and irradiating said mixture to cross-

Art Unit: 1732

link the PE chains, hence controlling the amount of free radicals by irradiation and antioxidant amount. It is noted that a medical implant must be oxidation and wear resistant in order to function as described. The purpose of vitamin E is to create an oxidation resistant product, hence it is submitted that the medical implant of Lidgren *et al.* ('315) is oxidation resistant in order to function as described. The purpose of using UHMWPE, which has large molecular weight, is to create a product that is wear resistant, hence it is submitted that the medical implant of Lidgren *et al.* ('315) is wear resistant in order to function as described. Furthermore, it is submitted that the medical implant of Lidgren *et al.* ('315) is sterile in order to function as a medical implant.

Regarding claims 1, 34-35, and 77, although Lidgren *et al.* ('315) teach doping a polymeric material (powder) with an antioxidant (vitamin E), Lidgren *et al.* ('315) do not teach doping a consolidated polymeric material with an antioxidant by diffusion. Hahn ('904) teaches a process for making a medical implant by either consolidating a polymeric material (UHMWPE) and doping said consolidated polymeric material with an antioxidant or as an equivalent alternative, doping said polymeric material and then consolidating said doped, polymeric material (see col. 3, lines 15-20 and col. 7, lines 24-47). Hahn ('904) teaches that both methods provide for antioxidant material to be present in the final, consolidated product. Further, Hahn ('904) teaches soaking said consolidated polymeric material in an antioxidant solution such that the soaking time, temperature and solution strength determine the doping level (see col. 3, lines 29-35). It is submitted that upon soaking said consolidated polymeric material in an antioxidant solution the laws of diffusion apply such that the antioxidant solution diffuses into the said consolidated polymeric material. Hence, it is submitted that based upon Fick's Laws on diffusion a gradient of antioxidant is formed in the consolidated polymeric material.

Additionally regarding claims 1, 34-35, and 77, Higgins teaches that it is known to first irradiate a consolidated polymeric material (3:1-37), and then to subsequently dope the medical implant with hydrogen in order to extinguish free radicals (3:25-45). In particular, Higgins teaches that irradiation produces free radicals in polymeric implants (2:14-35), and that free radicals crosslink with other local polymer chains (1:55-57), leading to a (desirable) improvement in the abrasion resistance (1:58-63), but that free radicals react with oxygen in vivo, producing a troublesome result (2:6-13).

Thus, one of ordinary skill at the time of the invention would have found it *prima facie* obvious to combine the method of Hahn with that of Lidgren and to perform irradiation prior to doping the implant with an antioxidant according to the method of Hahn in view of Higgins' suggestion that the crosslinking produced by irradiation is desirable because of the crosslinking and abrasion resistance that it produces, but that the free radicals should be extinguished prior to implantation in order to avoid in vivo oxidation.

In regard to claims 5-7 and 38-40, Hahn ('904) teaches soaking said consolidated polymeric material in an antioxidant solution such that the soaking time, temperature and solution strength determine the doping level (see col. 3, lines 29-35). Hence, it is submitted that soaking time, temperature and solution strength are result-effective variables. In re Antonie, 559 F.2d 618, 195 USPQ 6 (CCPA 1977). Therefore, it would have been obvious for one of ordinary skill in the art to have doped a consolidated polymeric material as an equivalent alternative to doping the polymeric material as taught by Hahn ('904) in the process of Lidgren *et al.* ('315) because, Hahn ('904) specifically teaches that such process step sequences are equivalent alternatives and also because both references teach the same polymeric material, UHMWPE, and

Art Unit: 1732

the same end-product (medical implant).

Specifically regarding claim 8, Lidgren *et al.* ('315) teach annealing at a temperature above the melting temperature of the consolidated polymeric material (see col. 6, lines 8-18).

Regarding claims 9-10, 12, and 30-31, Lidgren *et al.* ('315) teach UHMWPE (polyolefin) powder and an antioxidant (vitamin E, alpha-tocopherol) (see Abstract).

In regard to claims 11, Lidgren *et al.* ('315) teach a medical implant for a joint replacement, specifically a femoral component (see col. 1, lines 13-16 and 50-55).

Specifically regarding claims 13-19, and 21-26, Lidgren *et al.* ('315) teach gamma radiation of 3.3-100 Mrad in air and an inert atmosphere, *i.e.* nitrogen gas (fluid) and, remelting the irradiated polymer in a non-oxidative atmosphere, *i.e.* inert or vacuum (1% oxygen) to reduce the free radicals (see col. 2, lines 13-55).

Regarding claim 27, Lidgren *et al.* ('315) teach the use of a solvent (ethanol) (see col. 3, lines 10-15).

In regard to claims 28-29, Lidgren *et al.* ('315) teach diffusion of an antioxidant in a supercritical fluid such as, CO₂ (see col. 4, lines 62-65).

Specifically regarding claims 32-33, it is noted that the limitation are functional limitations. In a claim drawn to a process of making, it is the structure that carries patentability and not the functional limitation. Therefore, it would have been obvious for one of ordinary skill in the art to have made a non-permanent medical device, such as a tubing using the process of Lidgren *et al.* ('315) in view of Hahn ('904) because, Lidgren *et al.* ('315) teaches that the doped UHMWPE provides for improved properties that enhance the material's use as a biological material, hence providing for an improved product such as a catheter or a non-permanent

Art Unit: 1732

medical device.

4. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lidgren *et al.* (US Patent No. 6,448,315) in view of Hahn (US Patent No. 5,827,904), and Higgins (USPN 5753182), and in further view of Parth *et al.* (2002) (referenced as A11 in the IDS filed 7/16/2004).

Lidgren *et al.* ('315) in view of Hahn ('904) and Higgins ('182) teach the basic claimed process as described above.

Regarding claim 20, although Lidgren *et al.* ('315) in view of Hahn ('904) and Higgins ('182) teach treating UHMWPE with gamma radiation, Lidgren *et al.* ('315) in view of Hahn ('904) and Higgins ('182) do not teach e-beam radiation. However, the use of e-beam radiation as an equivalent alternative to gamma radiation (see Abstract and Conclusions) is well known as evidenced by Parth *et al.* (2002). Therefore, it would have been obvious for one of ordinary skill to have used e-beam radiation as an equivalent alternative to gamma radiation as taught by Parth *et al.* (2002) to treat UHMWPE in the process of Lidgren *et al.* ('315) in view of Hahn ('904) and Higgins ('182) because, Parth *et al.* (2002) specifically teach the use of e-beam radiation as an equivalent alternative to gamma radiation and also because all references teach similar materials and end-products.

5. Claims 3-4 and 36-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lidgren *et al.* (US Patent No. 6,448,315) in view of Hahn (US Patent No. 5,827,904), and Higgins (USPN 5753182), and in further view of Burstein *et al.* (US Patent No. 6,620,198).

Art Unit: 1732

Lidgren *et al.* ('315) in view of Hahn ('904) and Higgins ('182) teach the basic claimed process as described above.

Regarding claims 3-4 and 36-37, although Lidgren *et al.* ('315) teach a metallic/UHMWPE component (see col. 1, lines 14-20), Lidgren *et al.* ('315) in view of Hahn ('904) and Higgins ('182) do not teach compression molding a metallic/UHMWPE component. Burstein *et al.* ('198) teach compression molding a polymer element (140) (UHMWPE) and a metallic element (130) to form a medical component (see col. 5, lines 1-10). It is submitted that a metallic/UHMWPE component includes a metal/polymer interface. Therefore, it would have been obvious for one of ordinary skill in the art to have compression molded a polymer element and a metallic element as taught by Burstein *et al.* ('198) to form a medical component by the process of Lidgren *et al.* ('315) because, Burstein *et al.* ('198) teach that a metallic/polymer interface provides for an improved product having improved biological properties and also because Lidgren *et al.* ('315) teach a metallic/UHMWPE component (see col. 1, lines 14-20), hence teaching the desirability of a metallic/polymer interface.

6. Claims 41, 42, 45-49, 52-55, 57, 59-62, and 64-72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lidgren *et al.* (US Patent No. 6,448,315) in view of Hahn (US Patent No. 5,827,904).

Lidgren *et al.* ('315) teach the basic process for making a medical implant including, providing UHMWPE powder, mixing said powder with vitamin E (antioxidant) to reduce oxidation, irradiating said mixture with radiation, compression molding said irradiated mixture into said medical implant or machining medical implants from compression molded blocks of

Art Unit: 1732

said irradiated mixture, packaging said medical implant and sterilizing said package (see col. 4, line 45 through col. 5, line 10 and col. 5, line 66 through col. 6, line 8). Further, it is submitted that Lidgren *et al.* ('315) teach reducing the free radicals and irradiating said mixture to cross-link the PE chains, hence controlling the amount of free radicals by irradiation and antioxidant amount. It is noted that a medical implant must be oxidation and wear resistant in order to function as described. The purpose of vitamin E is to create an oxidation resistant product, hence it is submitted that the medical implant of Lidgren *et al.* ('315) is oxidation resistant in order to function as described. The purpose of using UHMWPE, which has large molecular weight, is to create a product that is wear resistant, hence it is submitted that the medical implant of Lidgren *et al.* ('315) is wear resistant in order to function as described. Furthermore, it is submitted that the medical implant of Lidgren *et al.* ('315) is sterile in order to function as a medical implant.

Regarding claims 41-42, 48-49, 55, and 62, although Lidgren *et al.* ('315) teach doping a polymeric material (powder) with an antioxidant (vitamin E), Lidgren *et al.* ('315) do not teach doping a consolidated polymeric material with an antioxidant by diffusion. Hahn ('904) teaches a process for making a medical implant by either consolidating a polymeric material (UHMWPE) and doping said consolidated polymeric material with an antioxidant or as an equivalent alternative, doping said polymeric material and then consolidating said doped, polymeric material (see col. 3, lines 15-20 and col. 7, lines 24-47). Hahn ('904) teaches that both methods provide for antioxidant material to be present in the final, consolidated product. Further, Hahn ('904) teaches soaking said consolidated polymeric material in an antioxidant solution such that the soaking time, temperature and solution strength determine the doping level (see col. 3, lines 29-35). It is submitted that upon soaking said consolidated polymeric material in an antioxidant

Art Unit: 1732

solution the laws of diffusion apply such that the antioxidant solution diffuses into the said consolidated polymeric material. Hence, it is submitted that based upon Fick's Laws on diffusion a gradient of antioxidant is formed in the consolidated polymeric material.

It would have been obvious for one of ordinary skill in the art to have doped a consolidated polymeric material as an equivalent alternative to doping the polymeric material as taught by Hahn ('904) in the process of Lidgren *et al.* ('315) because, Hahn ('904) teaches that such process step sequences are equivalent alternatives and also because both references teach the same polymeric material, UHMWPE, and the same end-product (medical implant). Furthermore, it is submitted that the medical implant of Lidgren *et al.* ('315) in view of Hahn ('904) is sterile in order to function as a medical implant and also because Lidgren *et al.* ('315) in view of Hahn ('904) teach treating UHMWPE with gamma radiation. Additionally, it would have been *prima facie* obvious to make the combination because it would be easier to treat or dope a solid part than a loose powder.

In regard to claims 45-47, 52-54, 59-61 and 65-67, Hahn ('904) teaches soaking said consolidated polymeric material in an antioxidant solution such that the soaking time, temperature and solution strength determine the doping level (see col. 3, lines 29-35). Hence, it is submitted that soaking time, temperature and solution strength are result-effective variables. In re Antonie, 559 F.2d 618, 195 USPQ 6 (CCPA 1977). Therefore, it would have been obvious for one of ordinary skill in the art to have doped a consolidated polymeric material as an equivalent alternative to doping the polymeric material as taught by Hahn ('904) in the process of Lidgren *et al.* ('315) because, Hahn ('904) specifically teaches that such process step sequences are equivalent alternatives and also because both references teach the same polymeric material,

Art Unit: 1732

UHMWPE, and the same end-product (medical implant).

Specifically regarding claim 68, Lidgren *et al.* ('315) teach annealing at a temperature above the melting temperature of the consolidated polymeric material (see col. 6, lines 8-18).

Regarding claims 69-70 and 72, Lidgren *et al.* ('315) teach UHMWPE (polyolefin) powder and an antioxidant (vitamin E, alpha-tocopherol) (see Abstract).

In regard to claim 71, Lidgren *et al.* ('315) teach a medical implant for a joint replacement, specifically a femoral component (see col. 1, lines 13-16 and 50-55).

Specifically regarding claims 57 and 64, Lidgren *et al.* ('315) teach gamma radiation of 3.3-100 Mrad in air and an inert atmosphere, *i.e.* nitrogen gas (fluid) and, remelting the irradiated polymer in a non-oxidative atmosphere, *i.e.* inert or vacuum (1% oxygen) to reduce the free radicals (see col. 2, lines 13-55).

7. Claims 43-44, 50-51, 56, 58, 63 and 73-75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lidgren *et al.* (US Patent No. 6,448,315) in view of Hahn (US Patent No. 5,827,904) and in further view of Burstein *et al.* (US Patent No. 6,620,198).

Lidgren *et al.* ('315) in view of Hahn ('904) teach the basic claimed process as described above.

Regarding claims 43-44, 50-51, 56, 58, 63, and 73-75, although Lidgren *et al.* ('315) teach a metallic/UHMWPE component (see col. 1, lines 14-20), Lidgren *et al.* ('315) in view of Hahn ('904) do not teach compression molding a metallic/UHMWPE component. Burstein *et al.* ('198) teach compression molding a polymer element (140) (UHMWPE) and a metallic element (130) to form a medical component (see col. 5, lines 1-10). It is submitted that a

Art Unit: 1732

metallic/UHMWPE component includes a metal/polymer interface. Therefore, it would have been obvious for one of ordinary skill in the art to have compression molded a polymer element and a metallic element as taught by Burstein *et al.* ('198) to form a medical component by the process of Lidgren *et al.* ('315) because, Burstein *et al.* ('198) teach that a metallic/polymer interface provides for an improved product having improved biological properties and also because Lidgren *et al.* ('315) teach a metallic/UHMWPE component (see col. 1, lines 14-20), hence teaching the desirability of a metallic/polymer interface.

8. Claims 76 and 80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lidgren *et al.* (US Patent No. 6,448,315) in view of Hahn (US Patent No. 5,827,904) and in further view of Burstein *et al.* (US Patent No. 6,620,198) and Ylanen *et al.* (US Patent No. 6,517,857 B2).

Lidgren *et al.* ('315) in view of Hahn ('904) and in further view of Burstein *et al.* ('198) teach the basic claimed process as described above.

Regarding claims 76 and 80, although Lidgren *et al.* ('315) teach a metallic/UHMWPE component (see col. 1, lines 14-20), Lidgren *et al.* ('315) in view of Hahn ('904) and in further view of Burstein *et al.* ('198) do not teach compression molding a metallic/ceramic component. Ylanen *et al.* ('857) teach that polymers, metals and ceramic are all alternative materials for making a medical component. Therefore, it would have been obvious for one of ordinary skill in the art to have compression molded a ceramic element (non-metallic) and a metallic element to form a ceramic/metallic interface by the process of Lidgren *et al.* ('315) in view of Hahn ('904) and in further view of Burstein *et al.* ('198) and Ylanen *et al.* ('857) because, Ylanen *et al.* ('857)

Art Unit: 1732

specifically teach that polymers, metals and ceramic are all alternative materials for making a medical component, whereas Lidgren *et al.* ('315) teach a medical component.

Response to Arguments

9. Applicant's arguments filed 12 March 2007 have been fully considered but they are not persuasive. The arguments appear to be on the following grounds:

- a) Applicants submit that there is no teaching of a “gradient of antioxidant in the consolidated polymeric material” because Lidgren requires mixing of UHMWPE powder with an antioxidant prior to consolidation.
- b) Applicants reiterate that the Examiner has not addressed the new and unexpected results of the instant methods, such as lower wear resistance, which is produced because of an increased cross-link density. Applicants assert that contrasting of Example 4 and Example 15 shows that doping of consolidated UHMWPE produces better wear resistance than consolidation of doped UHMWPE powders. Because the claimed invention provides UHMWPE with new and unexpected results, the invention is not obvious as per the dictates of MPEP 2144.04(IV)(C).
- c) The references are not combinable without hindsight.

10. These arguments are not persuasive for the following reasons:

- a,b) The unexpected result that appears to be asserted is that doping of a consolidated part provides improved wear resistance over doping prior to irradiation because doping prior to irradiation interferes with the process of cross-linking which occurs during irradiation (page 13 of the 12 March 2007 reply and page 4, paragraph 5 of the declaration under 37 CFR 1.132 filed

Art Unit: 1732

21 April 2006). This assertion of an unexpected result appears to be presented to overcome a position set forth in previous actions that doping of particles and doping of a consolidated material are equivalent methods, the only difference being drawn to a difference in the order of process steps, supported by MPEP 2144.04(IV)(C) and the case law cited therein.

As noted previously on page 10 of the action mailed 30 May 2006, the objective evidence of the new or unexpected results should be commensurate in scope with the claims which the evidence is offered to support. In this case, various orders of steps are sought (see page 10 of the 30 May 2006 action for a description), and the assertions of criticality or unexpected results appear to support only some of the independent claims where it is claimed that irradiation precedes doping. Thus, the unexpected results and assertions of criticality are still incommensurate with various independent claims in which doping precedes irradiation. With regard to these claims, the Examiner reiterates the comments set forth previously that the evidence should be commensurate in scope with the claims and that selection of any order of performing process steps is prima facie obvious in the absence of new or unexpected results (see page 10 of the 30 May 2006 non-final rejection).

With regard to the assertions of criticality of irradiation and subsequent doping with Vitamin E, the Examiner provides the new reference to Higgins to rebut Applicants' position. As set forth above, Higgins teaches that it is known to first irradiate a consolidated polymeric material (3:1-37), and then to subsequently dope the medical implant with hydrogen in order to extinguish free radicals (3:25-45) in a process similar to the extinguishing of free radicals by Vitamin E doping. In particular, Higgins teaches that irradiation produces free radicals in polymeric implants (2:14-35), and that free radicals crosslink with other local polymer chains

Art Unit: 1732

(1:55-57), leading to a (desirable) improvement in the abrasion resistance (1:58-63), but that free radicals react with oxygen in vivo, producing a troublesome result (2:6-13). While Lidgren teaches that free radicals are extinguished by doping with Vitamin E and then irradiating, Higgins teaches that a desirable result is provided by first irradiating and crosslinking, and then subsequently extinguishing free radicals by doping the polymeric material with hydrogen. While it would not be appropriate to rely solely on case law as the rationale to support an obviousness rejection where the applicant has demonstrated the criticality of a specific limitation (See MPEP 2144.04), in this case Higgins suggests the particular limitation of irradiating prior to extinguishing free radicals.

c) In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

Art Unit: 1732

In this case, it is suggested by Hahn that the step of doping with an antioxidant can be performed at various points in the fabrication process in order to reduce free radicals.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew J. Daniels whose telephone number is (571) 272-2450. The examiner can normally be reached on Monday - Friday, 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Johnson can be reached on (571) 272-1176. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

A handwritten signature in black ink, appearing to read 'Matthew J. Daniels', with a stylized flourish at the end.

Matthew J. Daniels

A.U. 1732

7 June 2007